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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/715,853	11/17/2000	Ashvin H. Desai	010284-0269451	8968

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EXAMINER	
PATEL, NIHIR B	

ART UNIT	PAPER NUMBER
3772	

DATE MAILED: 10/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

NT

Office Action Summary	Application No.	Applicant(s)	
	09/715,853	DESAI, ASHVIN H.	
	Examiner	Art Unit	
	Nihir Patel	3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08.07.2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10,15,17,20,21,24,25,30,33 and 37-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10,15,17,20,21,24,25,30,33, and 37-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim **43** is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 43 contains subject matter **(the phrase "entirely")** was not descried in the specification. On page 5 of the specification the applicant states that **"...the microspheres is constructed of a biodegradable material."**, but does not mention entirely.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims **10, 15, 17, 24, 25, 30, 33, 37-39, 41 and 43** are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al. (US 5,472,441) in view of Mulier et al. (US 5,807,395).

5. **As to claim 43**, Edwards et al. discloses a method for treating a localized portion of body tissue in a body via inserting a needle apparatus in body tissue, the apparatus including at least

one hollow needle core for delivering an electrically conductive substance into the body tissue in the form of a chemotherapeutic fluid, whereby the substance is limited to a localized portion of body tissue (column 7, lines 45-55; column 8, lines 55-65; column 9, lines 22-25; column 10, lines 1-15; column 13; column 16; column 17, lines 1-5; and column 18, lines 5-13). Further, Applicant is directed to column 16, lines 15-20 where the electrically conductive solution is discussed.

The substance is conveyed in biodegradable microsphere containers, which "are tiny hollow metallic spheres...[with] a thin coating **104** [that] is provided around the entire surface of each of the microspheres **101**" (column 16, lines 35-41). Edwards further discloses, "the coating **104** could simply be biodegradable for chemical stripping by the body's natural fluids...[for] site specific application of the therapeutic drug within the neoplasm...as well as an accurately controlled time release of the drugs into the neoplasm" (column 16, lines 47-52). The definition doesn't include an inherent meaning that anything biodegradable must be "entirely" biodegradable and thus, broadly and reasonably interpreted by the examiner, the microspheres of the prior art meet the claim limitations of "biodegradable microsphere containers".

In addition, Edwards et al. recites guiding the needle apparatus to a desired volume tissue in need of treatment (column 6, lines 55-65 and column 7, lines 50-55), applying the substance to the volume of tissue through the needle apparatus, determining that the volume of tissue is penetrated by the substance (as discussed throughout the disclosure), and applying RF energy to the substance through an RF electrode to ablate the volume of tissue, where the substance serves an electrode extension conducting the RF energy throughout the volume (as recited throughout the disclosure with emphasis on columns 15-16).

However, Edwards et al. do not explicitly recite a non-invasive imaging technique for guiding the needle However, non-invasive imaging techniques (such as MRI, ultrasound, etc.) for guiding needles as well as chemotherapeutic fluids in the form of a gel suspension are extremely well known in the art. Specifically, Mulier et al. teaches the use of "ultrasound guidance" of the needle **206** during the medical procedure (column 18, lines 25-43).

Thus, it would be obvious to one with ordinary skill in the art to use a non-invasive imaging technique, such as ultrasound guidance, for the purpose of reducing trauma due to invasive guidance procedures, as taught by Mulier et al.

5. **As to claim 10**, Edwards et al. as modified discloses that as applied to **claim 43** as well as a needle apparatus that includes a biopsy needle guide through which the hollow core needle is inserted and the hollow core needle functions as the RF electrode (columns 13, 15, 16, etc.).

6. **As to claim 15**, Edwards et al. as modified discloses that as applied to **claim 43** as well as the use of imaging contrasting agents (column 17, lines 1-4). Therefore, it is within the scope of the modification to use imaging contrast agents for use in determining the volume of body tissue penetrated.

7. **As to claim 17**, Edwards et al. as modified discloses that as applied to **claim 43** as well as necrosis agents and the use of RF (column 10, lines 55-58 and column 11; delivering ablation energy to the tissue acts as the necrosis agent).

8. **As to claim 24**, Edwards et al. as modified discloses that as applied to **claim 43** as well as the method applied for treatment of a body part, namely the lung and breast (column 4, line 14).

9. **As to claim 25**, Edwards et al. as modified discloses that as applied to **claim 24** as well as inserting that is accomplished using an approach selected form the group of percutaneous, laparoscopic and endoscopic (column 6, lines 55-65).

10. **As to claim 30**, Edwards et al. as modified discloses that as applied to **claim 43** as well as guiding that is further performed using a device selected from the group of biopsy apparatus, laparoscope, endoscope, hysteroscope, magnetic resonance imaging (MRI), computed tomography scan (CT scan) and ultrasound imaging apparatus (column 6, lines 55-65).

11. **As to claim 33**, Edwards et al. as modified discloses that as applied to **claim 43** as well as inserting that is performed by at least one method selected from the group of percutaneous, through incision, and through a natural body opening, and a laparoscopic approach, as stated throughout the specification.

12. **As to claim 37**, Edwards et al. as modified discloses that as applied to **claim 43** as well as chemotherapeutic agents such as tissue necrosing agents (column 11). Further, binding agents would be obvious to increase the effectiveness of the treatment.

13. **As to claim 38**, Edwards et al. as modified discloses that as applied to **claim 43** as well as microspheres that have a gas (some air inclusion is inherent). However, the solution of Edwards et al. is comprised of microspheres (column 16).

14. **As to claim 39**, Edwards et al. as modified discloses that as applied to **claim 38** as well as a gas that is selected form the group of air, helium, fluorocarbon, and carbon dioxide.

15. **As to claim 41**, Edwards et al. as modified discloses that as applied to **claim 43** as well as a conductive component that is selected from the group consisting of conductive polymers,

conductive agents, conductive elements, conductive particles and metallic suspensions (column 16, line 16).

16. Claim **21** rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al. (US 5,472,441) in view of Mulier et al. (US 5,807,395) as applied to claim **43** above, and further in view of Lax et a. (US 5,486,161).

17. **As to claim 21,** Edwards discloses the applicant's invention as claimed with the exception of providing a method step wherein the target tissue is a prostate, and wherein the method is for treating a condition selected from the group comprising of benign prostatic hyperplasia (BPH) and prostate cancer and is accomplished by a method selected from the group consisting of transrectal, transurethral and transperineal approaches. Lax discloses a medical probe device and method that does provide a method step for treating a condition selected from the group comprising of benign prostatic hyperplasia (BPH) and prostate cancer (see field of invention) and is accomplished by transrectal approach, which is well known in the art. Therefore it would have been obvious to modify Edward's invention by providing a method step for treating a condition selected from the group comprising of benign prostatic hyperplasia (BPH) and prostate cancer (see field of invention) and is accomplished by transrectal approach as taught by Lax.

18. **Claims 20, 40** and **42** are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al. (US 5,472,441) in view of Mulier et al. (US 5,807,395), as applied to **claims 10, 15, 17, 21, 24, 25, 30, 33, 37-39, 41** and **43** above, and further in view of Roskos et al. (US 6,224,883 B1).

19. **As to claim 20**, Edwards et al. as modified discloses that as applied to **claim 43**. Edwards et al. recites the use of microspheres in column 16. However, Edwards et al. do not explicitly recite that the microspheres are contained in a substance for providing image enhancement, such as a gel suspension. On the other hand, Roskos et al. teaches a treatment substance that is in the form of a gel suspension. Therefore, it would be obvious and within the scope of the invention to also use microspheres in a gel suspension for the conductive solution. Thus, it is within the scope of the invention and obvious to one with ordinary skill in the art to use microspheres (in a gel suspension) for providing image enhancement when the imaging technique is ultrasound (column 16 and column 17, lines 1-5).

20. **As to claim 40**, Edwards et al. as modified discloses that as applied to **claim 37**. However, Edwards et al. do not explicitly recite a treatment substance having a binding agent and that binding agent is selected form the group of biomaterial, polymer, biodegradable polymer, a suspension agent, a derivative of a protein, fat, collagen and oil. On the other hand, Roskos et al. teaches a treatment substance that is in the form of a gel suspension, wherein the gel suspension further has a binding agent and that binding agent is selected form the group of biomaterial, polymer, biodegradable polymer, a suspension agent, a derivative of a protein, fat, collagen and oil, as stated throughout specification. Therefore, it would be obvious to one with ordinary skill in the art at the time the invention was made to modify the invention of Edwards et al. to use a gel suspension for the purpose of increasing viscosity allowing more controlled delivery, as taught by Roskos et al.

21. **As to claim 42**, Edwards et al. as modified disclosed that as applied to **claim 43**. Roskos et al. teaches the use of a chemotherapeutic fluid, such as cisplatin, in the form of "gel

formulations for direct injections into a neoplastic lesion or surrounding tissue" (Abstract), which are biodegradable materials fully capable of being contained within the microsphere containers of Edwards et al. (as well as the other way around, i.e. the gel suspension containing microsphere containers). This modification would necessarily include the conductive gel within a biodegradable container, wherein biodegradable containers are discussed in column 16, lines 47-50 of the prior art specification of Edwards et al.

Response to Arguments

22. Applicant's arguments filed August 7th, 2006 have been fully considered but they are not persuasive. The applicant argues that Edwards does not describe a biodegradable microsphere container. The examiner disagrees. The microspheres of Edwards "are tiny hollow metallic spheres... [with] a thin coating **104** [that] is provided around the entire surface of each of the microspheres **101" (see column 16 lines 35-41)**. Edwards further discloses, "the coating **104** could simply be biodegradable for chemical stripping by the body's natural fluids...[for] site specific application of the therapeutic drug within the neoplasm...as well as an accurately controlled time release of the drugs into the neoplasm **(see column 16 lines 47-52)**.

In addition, the applicant states that Edwards teaches away from biodegradable microspheres." The examiner disagrees. Not only does Edwards provide adequate disclosure, but also motivation to use such a type of material to produce microspheres, at least in part. Since the applicant's specification has not stated that the microspheres are entirely constructed of biodegradable material, the examiner has broadly and reasonably interpreted the microspheres of the prior art meet the claim limitations of "biodegradable microsphere containers".

The applicant also argues that biodegradable must mean entirely. The examiner disagrees. The definition doesn't include an inherent meaning that anything biodegradable must be "entirely" biodegradable.

Terminal Disclaimer

23. The terminal disclaimer filed on August 7th, 2006 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of December 12th, 2005 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nihir Patel whose telephone number is (571) 272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nihir Patel
Art Unit 3772